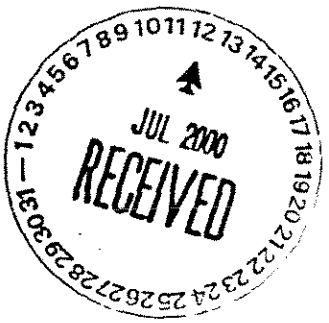
Case Review

Eric Jeffries

Mass Casualty Insurance Co., Claim # 0641734



July 7, 2000

James R. Garb, M.D.

SS# [redacted]

Introduction

This report is based on a review of the medical records furnished to me on Eric Jeffries as requested by Lucinda Palmer of Disability Management Services, Inc.

The purpose of this report is to assist in the understanding of Mr. Jeffries' medical condition and any basis for occupational impairment as a result of this. The report addresses seven specific questions posed by Ms. Palmer.

Case Summary

Mr. Eric Jeffries is a 39 year old banker who claims to be totally disabled as a result of having received the hepatitis B vaccine in July of 1997. His symptom complex has consisted of arthralgias, myalgias, abdominal pain, oral ulcerations, headaches, cognitive difficulties and fatigue. In September of 1998, he gave up his job as a Senior vice president of Structured Finance in a large financial service institution.

Questions Posed by Ms. Palmer

1. ***What medical diagnosis or diagnoses are reflected in these records, based on what objective information and clinical studies?***

Mr. Jeffries has seen 21 physicians across the United States and in the United Kingdom in pursuit of a definitive diagnosis and treatment of his medical condition. Much of this apparently was at his own expense. In reviewing these voluminous medical records, it is apparent to me that Mr. Jeffries has received unusually high quality medical care. I was impressed with the thoroughness of the evaluations he received from all physicians who saw him.

Despite all of the evaluations that Mr. Jeffries has undergone, however, I believe that it is not possible at this time to make a single, definitive, unifying diagnosis that would fully explain his condition Indeed, this seems to be the conclusion of many of the physicians whom he saw.

I believe that the following diagnoses can be made with a high degree of medical certainty based on objective laboratory, radiological or tissue pathology data.

1. **Gilbert's Syndrome**, a benign congenital error of metabolism resulting in mildly elevated unconjugated bilirubin levels, as evidenced in this patient by repeatedly elevated bilirubin determinations
2. **Partial empty sella syndrome**, where the sella turcica is filled with cerebrospinal fluid, causing the pituitary gland to be flattened and pushed to one side, although

with normal functioning, as supported in this patient by MRI findings and a normal endocrine work-up

3. **Hepatic hemosiderosis and mild steatosis,** as supported in this patient by a liver biopsy. I believe these findings are most likely due to either alcoholic liver disease or idiopathic hemochromatosis, as reported by the pathologist. Porphyria cutanea tarda was also mentioned as a possible cause of these hepatic tissue findings, but has effectively been ruled out by subsequent diagnostic studies.

The following diagnoses are made with a moderate degree of medical certainty, based on clinical findings as described by Diya Mutasim, M.D., Professor and Chairman of the Department of Dermatology at the University of Cincinnati:

4. **Bacterial Folliculitis**
5. **Recurrent Aphthous Lesions (Stomatitis)**

The following diagnosis is made with a fair degree of medical certainty, however it remains a clinical diagnosis, and one of exclusion. Nevertheless, I believe it is the most likely diagnosis for Mr. Jeffries' recurrent abdominal symptoms. I say this because extensive evaluations by several gastroenterologists, including radiologic studies, direct visualization and biopsies of virtually his entire GI tract, have excluded most alternative diagnoses, both common and rare.

6. **Functional Bowel Disorder**

The greatest diagnostic difficulty in this case centers around the suggestion of some poorly defined type of auto-immune process. There are some objective diagnostic tests that suggest that such a process may be present. These include a low total complement level (CH100), although specific components of complement, C3 and C4, have been normal; an elevated cold agglutinin titer (> 1:2048 on 7/23/79); a positive HLA B-27 antigen; a single elevated CK level of 360 (normal 48 - 251) on 7/17/97; and a positive thyroid peroxidase antibody (9/14/99). Numerous other autoimmune antibody studies, as well as repeated studies looking for an inflammatory process, have all been negative. The clinical significance of these tests remains unclear. They certainly do not point to any single diagnosis.

Micheal Luggen, M.D., a rheumatologist and clinical immunologist who has had the most contact with Mr. Jeffries, felt he was unable to make a precise diagnosis of his illness (11/9/99).

He has been seen by four other immunologists, who have made the following diagnoses:
Deborah Fritz, M.D.: Generalized myalgias and myofascial pain 4/24/98)
Leonard Calabrese, D.O.: Non-inflammatory rheumatism (12/21/98)

Burton Waisbren, M.D.: Postvaccinal encephalomyelitis and acquired autoimmunity (9/99)

Dr. G.P. Spickett: Vaccine-induced aberrant immune response (1/29/00)

These possible diagnoses are discussed more fully in the response to questions 5 and 6 below. At this point, I think one can only say that Mr. Jeffries may have:

7. **A poorly characterized, non-inflammatory auto-immune syndrome of uncertain etiology, possibly related to hepatitis B vaccination**

2. ***Are additional referrals to other experts, evaluations or tests indicated to more completely understand the diagnoses?***

Mr. Jeffries has had many blood tests performed. Whenever multiple tests are done on an individual, there is the possibility that some of them may be "abnormal" by chance alone, in other words, a false positive test. This phenomenon is related to the sensitivity and specificity of the individual tests. It would be beneficial to repeat the immunologic tests that have been abnormal in the past to ascertain whether they remain abnormal. These include the total complement level, cold agglutinin, thyroid peroxidase antibody, and creatinine kinin. It might also be worthwhile to repeat the HLA B-27 antigen to verify this result, and the C3 and C4 levels to see if they have remained normal.

I believe that Mr. Jeffries should be evaluated by a clinical psychologist who specializes in chronic pain, and should have a full battery of neuro-psychiatric testing to better characterize and document any possible cognitive deficits and to further explore his response to his pain syndrome. It would appear that Mr. Jeffries has become somewhat obsessed with his illness, spending considerable time researching it on the internet (by some accounts, up to eight hours a day) and traveling around the country, and on two occasions to Great Britain, to see numerous specialists. This suggests the possibility of a somatoform disorder, or at least a psycho-social component resulting in magnification of his underlying symptoms, possibly related to a potential class action lawsuit against the hepatitis B vaccine manufacturer.

I do not believe that any further medical tests are indicated at this time.

3. ***What has been the treatment to date of Mr. Jeffries? Has this treatment been progressive and focused on reducing symptoms and supporting Mr. Jeffries' return to work?***

In the early phase of Mr. Jeffries' illness, before most of the diagnostic testing had been done, treatment was undertaken with a variety of agents, in part to improve his symptoms, and in part as diagnostic trials to rule out various diagnostic possibilities. Thus, he was treated with oral prednisone, colchicine, naprosyn, vicodin, amitryptilene, Zoloft, Neurontin, Trental,

sulfasalazine, Valtrex, and intramuscular gamma globulin, all with no obvious benefit. He had a trial of acupuncture and Chinese herbs, although these specific treatment records were not available for review. His abdominal pain was treated with Prilosec,

Although his treatment has been somewhat complicated by the number of physicians he has seen, I do believe that it was progressive and entirely reasonable during this phase of his illness. In my opinion, Dr. McClellan deserves considerable credit for coordinating this treatment effort.

After these therapeutic interventions successively failed, and various possible diagnoses were systematically eliminated, his treating physicians appear to have concluded that no specific treatment would be beneficial, and so little has been done for Mr. Jeffries in the second phase of his illness to provide him with supportive measures that might allow him to better cope with his condition and even return to work, despite his ongoing symptoms. Dr. Calabrese, on 12/21/98, recommended a cautions, progressive exercise program as vital to Mr. Jeffries' recovery. He stated his belief that problems with coping and deconditioning would likely complicate this recovery. I see no mention in the records of efforts to address these serious rehabilitation issues, such as behavioral medicine support, progressive physical therapy, or a work hardening program.

4. ***What objective medical findings support occupational limitations or restrictions, if any, are found in these records? Is there evidence that Mr. Jeffries should not work in any capacity or does he have the capacity to work in a part time or full time basis?***

Mr. Jeffries' complaints are entirely subjective.

Throughout this record, there are numerous accounts of physical examinations performed, with no significant persistent findings described other than some right upper quadrant abdominal tenderness and, at times, a slow gait. In fact, it is most often recorded that Mr. Jeffries looks well on physical examination. There have been no findings of arthritis to support his complaints of joint pains. In fact, despite his complaint of pain, there has been remarkably little prescription of analgesic medication throughout the course of his symptom complex.

As already described in the response to question 1, despite multiple laboratory, radiologic, endoscopic, and nerve conduction tests, the only objective, abnormal test results are a few immunologic tests that are of uncertain significance. These test results in and of themselves do not dictate that Mr. Jeffries needs to be restricted or limited from performing the duties of his former occupation.

Mr. Jeffries is apparently able to utilize the internet in a significant way, and to travel around the country and to Great Britain to see various physicians. I do not believe the objective

medical record supports the contention that Mr. Jeffries is unable to work in any capacity, or specifically in the capacity of vice president of a financial institution.

5. ***What are the potential side effects of Hepatitis A and B immunizations, and what is the incidence of these side effects?***

Hepatitis A Vaccine (Havrix, Smithkline Beecham)

According to information supplied by the manufacturer based on clinical trials involving over 31,000 individuals, the following reactions occur in 1% to 10% of individuals: induration, swelling or redness of the injection site; fatigue, fever, malaise, anorexia and nausea. The following reactions occur in less than 1% of individuals: hematoma at injection site, prurutis, rash, urticaria, pharyigitis, respiratory tract infections, abdominal pain, diarrhea, dysgeusia, vomiting, arthralgia, elevation of creatinine phosphokinase (CK), myalgia, lymphadenopathy, hypertonia, insomnia, photophobia and vertigo.

Since the marketing of the vaccine, lymphedema has been reported rarely as a side effect.

The following rare events have been reported, although no causal relationship with the vaccine has been established: anaphylaxis, somnolence, syncope, jaundice, hepatitis, erythema multiforme, hyperhidrosis, angioedema, dyspnea, lymphadenopathy, convulsions, encephalopathy, dizziness, neuropathy, myelitis, paresthesias, Guillian-Barr— syndrome, multiple sclerosis.[1]

Hepatitis B Vaccine (Engerix B, Smithkline Beecham)

According to information supplied by the manufacturer based on clinical trials involving over 13,000 doses, the following reactions occur in 1% to 10% of individuals: induration, swelling or redness of the injection site, fever, headaches, dizziness. The following reactions occur in less than 1% of individuals: pain, pruritis, ecchymosis of the injection site, sweating, malaise, chills, weakness, flushing, tingling, hypotension, , influenza like symptoms, upper respiratory illness, nausea, anorexia, abdominal pain/cramps, vomiting, constipation, diarrhea, lymphadenopathy, pain or stiffness in arm, shoulder or neck, arthralgia, myalgia, back pain, rash, urticaria, petechiae, pruritis, erythema, somnolence, insomnia, irritability, agitation.

Hypersensitivity reactions have been reported, including anaphylaxis, erythema multiforme including Stevens Johnson syndrome, angioedema, arthritis. An apparent hypersensitivity syndrome (serum sickness-like) of delayed onset has been reported days to weeks after vaccination. This syndrome includes: arthralgia/arthritis (usually transient), fever and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum.[2]

In reviewing the more recent medical literature, there are numerous case reports of immunologic type reactions following administration of the hepatitis B vaccine. Some of these reactions include reactive arthritis, rheumatoid arthritis, Reiter's Syndrome, cryoglobulinema, and vasculitis.[3,4,5,6,7,8,9,10] Neurologic reactions have been reported rarely, including facial palsy, transverse myelitis, CNS demyelinization, acute cerebellar ataxia and ophthalmologic complications.[11]

The Vaccine Safety Committee of the Institute of Medicine examined four types of evidence to determine if a causal association exists between the administration of certain types of vaccines and selected adverse experiences. They considered biologic plausibility, case reports, case series and uncontrolled observational studies, controlled observational studies, and controlled clinical trials. The committee concluded that the evidence is inadequate to accept or reject a causal relation between hepatitis B vaccine and Guillian-Barr— syndrome, optic neuritis, multiple sclerosis or transverse myelitis.[12]

6. ***Does the record reflect a causal relationship between the onset of Mr. Jeffries' problems and the immunizations?***

The record indicates that some of Mr. Jeffries' symptoms had their onset several years prior to his receiving the hepatitis vaccines in July of 1997. His abdominal pain syndrome, intermittent aphthous stomatitis, skin lesions and Gilbert's syndrome appear to have been noted well before his hepatitis vaccinations.

There is a temporal relationship between the administration of the hepatitis A and hepatitis B vaccines and the development of his reported headaches, sweats, arthralgias, myalgias which had their onset within about one week.

Isolated case reports of adverse events occurring in temporal relationship to vaccination do not prove a causal relationship. One problem in interpreting these events is that over 600 million doses of hepatitis B vaccine have been administered world wide, and these rare kinds of immunologic events occur spontaneously in unvaccinated populations.[13] Thus it is difficult to establish with certainty that these rare events are related to the vaccine. People who are HLA-B27 positive, as is Mr. Jeffries, may be more susceptible to this type of reaction.

Grotto et al reviewed the literature on the major adverse reactions to yeast derived hepatitis B vaccines in 1998.[14] They described serious reactions including immediate reactions (anaphylaxis and urticaria) and delayed reactions, which included erythema nodosum, lichen planus, rheumatic, vasculitic (including Systemic Lupus Erythematosis and glomerulonephritis), hematologic, ophthalmalogic and neurologic reactions. It is noteworthy that Mr. Jeffries' symptom complex is not typical of any of these symptoms or syndromes. The authors concluded ~~that there may be a possible etiologic link between these adverse~~

effects and the hepatitis B vaccine, and that these effects are very rare, and may, in part, be immune mediated.

In Canada, 30 self-reported cases of chronic fatigue syndrome were alleged to be secondary to hepatitis B vaccination. A working group on that possible association concluded that there is no evidence of a causal relationship between hepatitis B vaccination and CFS.[15]

The physician who has the greatest degree of certainty about a causal relationship between the hepatitis B vaccine and Mr. Jeffries' symptoms is Dr. Burton Waisbren. The evidence he presents to support this view consists of anecdotal case reports. No controlled clinical trials have been undertaken to investigate this question. The other physicians, including other immunologists, seem less certain that a causal relationship exists. From the records available to me, it appears that some of these physicians have agreed that Mr. Jeffries' illness could possibly be related to the hepatitis B vaccine, largely on the force of Dr. Waisbren's arguments.

I discussed this question with Donald Craven, M.D., an Infectious Disease specialist and immunologist in Boston who has lectured about the hepatitis B vaccine. He believes there may be a relationship between the hepatitis B vaccine and rare autoimmune illnesses, however the risk is "very low". He believes that some patients may have underlying disease processes that may be accelerated by the vaccine.

In summary, I believe that, excluding those symptoms which had their onset prior to 1997, the record in this case neither proves nor disproves a causal relationship between Mr. Jeffries' other symptoms and the hepatitis B or hepatitis A vaccines he received in 1997.

7. ***If he is medically impaired from working now, what would be reasonable expectations for Mr. Jeffries being able to return to his occupation, in what time frame?***

Again, the totality of these records do not indicate to me that Mr. Jeffries currently is unable to perform the duties of his occupation. Unless disability is supported by rigorous neuro-psychological testing, I feel he could resume work at any time.

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SS # 029-34-4417

7/7/00
July 7, 2000

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